

MC PHARMA (PTY) LTD

REG. NO: 1999/009355/07

Providers of Medicine Regulatory Affairs Intelligence

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***CO-DEVELOPING CUSTOMER SPECIFIC SOLUTIONS.....
.....IN PARTNERSHIP WITH YOUR COMPANY'S GOALS.***

MC Pharma (Pty) Ltd., is a company licensed in terms of Section 22C of the Medicines and Related Substances Act 101 of 1965, and offers the services of a contract Applicant and Holder of the Registration Certificate on behalf of a Principal (product owner).

MC Pharma does not own, wholesale or distribute product and the Principal is at all times deemed to be the owner of the medicinal product(s). Commercialization activities are delegated, by means of agreements, to competent and licenced companies in South Africa.

MC Pharma (Pty) Ltd. acts as:-

- ***Applicant*** for pre-registered medicinal product applications, MC Pharma will submit an application for the registration of a medicinal product and act as Applicant for the duration of the medicine registration review process and until registration has been granted by the Regulatory Authority.
- ***Holder of the Registration Certificate.*** MC Pharma (Pty) Ltd will take responsibility for a medicinal product in a relationship that is free from commercial conflicts of interest, whilst allowing the "Principal" the freedom to place, and reassign the distribution rights for the medicinal product. MC Pharma will be responsible for all regulatory aspects of the medicine, including quality, safety and compliance with the conditions of registration. Technical agreements with all contract acceptors (manufacturer's; packers; analytical laboratories; warehouse, distribution facilities and marketing agents) enable MC Pharma to carry out and fulfill regulatory obligations.

Industries serviced include:-

- Pharmaceutical
- Health Products and Complementary medicines
- Veterinary
- Dental
- Medical devices
- Foodstuffs and cosmetics

MC PHARMA REGULATORY LICENCES

| <u>Authority</u> | <u>Type of Licence and date of Issue</u> | <u>Licence No</u> |
|-------------------------------|---|--------------------------|
| The Department of Health | Manufacturing Pharmacy dd 5/7/2004 | GP00036M |
| The Medicines Control Council | Licence to manufacture medicines dd 13/7/2004 | 0000000253 |
| | Licence to Import dd 10/04/2006 | 000000253.-.5 |
| SA Pharmacy Council | Certificate of recording of a Manufacturing Pharmacy dd 16/8/2004 | Y50668 |

OTHER SERVICES INCLUDE:

1. **Reviewing** formulation **ingredients** for claim and labeling compliance;
2. **Advertising compliance:** avoid the embarrassment and consequences of having a published advertisement found to be in conflict with local requirements. We screen promotional material giving confidence that marketing and advertising complies with local regulatory standards;
3. **Regulatory liaison** with the Regulatory Authority(ies);
4. **GMP and Quality Assurance** consultations;
5. **GMP assessments** of manufacturing, packaging and distribution facilities;
6. **Technical agreements** with 3rd party contractors: we will facilitate in the setting up of and establishing the required technical agreements with: -
 - Manufacturers,
 - Laboratories,
 - Warehouses,
 - Distributors,
 - Printers,
 - Advertising agencies

LOCATION

MC Pharma is an administrative office situated in Pretoria, the administrative capital of South Africa and the location of the Department of Health: Medicines Regulatory Authority and the SA Pharmacy Council. We have ready access to these departments for regular consultations, discussions and resolutions in respect of regulatory matters.

Client confidentiality is unequivocally maintained and internal quality systems assure complete client confidence. Through our service commitment to our clients, we are proud of the long-term relationships we have established and maintained through the years.

CONTACT US

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